IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re. Patent Application of Thierry-Palmer, et al.
USSN 10/617,254
Filed: July 11, 2003
Title: METHOD FOR IDENTIFYING SALT-SENSITIVE PERSONS

Letter Submitting documents:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

1) A request for extension of time along with a check in the amount of $60,00 attached thereto.

2) A Brief on Appeal. Attached to this letter is a check in the amount of $250.00 in payment therefor.

3) An amendment to correct dependency.

The commissioner is authorized to debit Deposit Account 08-1652 in any additional amounts required to fully pay all fees or to credit any over-payment to said account.

Respectfully submitted,

Glenna Hendricks, Reg. No. 32,535

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re. Application of Thierry-Palmer, et al. Art Unit 1651
USSN 10/617,254 Examiner Lankford
Filed: July 11, 2003
Title: METHOD FOR IDENTIFYING SALT-SENSITIVE PERSONS

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

This is an appeal from the rejection of claims 5 to11, all of the claims pending in the current application. The amendment after final was not entered. A clean copy of all of the claims as amended after the first Office Action and after the Advisory Action in accord with a discussion with Examiner Lankford is attached as Appendix 1. No claims have been allowed.

REAL PARTY IN INTEREST:

The real party in interest is Morehouse School of Medicine in Atlanta, Ga. The inventors are employees of that institution.

RELATED APPEALS AND INTERFERENCES:

There are no related appeals or interferences.

STATUS OF THE CLAIMS:

Claims 1-4 have been cancelled.

Claims 5-11 were previously added and have been amended only to correct dependency with filing of this Brief, since the amendment after final was not entered.

STATUS OF AMENDMENTS:

The amendment after final has not been entered. Hence, claims 5-11 as amended after final are not presented. The claims have been amended and it appears, from the discussion with Examiner Lankford, that amendments relating to dependency would be entered. Otherwise, the claims remain as presented after the first action on the merits.

SUMMARY OF THE CLAIMED SUBJECT MATTER:

Claims 1, 9 and 11 claim a kit for measurement of vitamin D binding proteins in urine as a marker for salt sensitivity. The kits comprise radiolabeled 25-hydroxyvitamin D_3, unlabeled 25-hydroxyvitamin D_3 and instructions for the measurement of vitamin D binding proteins in urine as a marker for salt sensitivity in

individuals. (See the paragraph bridging pages 2 and 3.) It has been shown that, particularly in the black community, vitamin D binding in the urine correlates with development of high blood pressure. As indicated in the specification, the object of the invention is to screen populations to determine likelihood of developing high blood pressure associated with salt sensitivity. (See first paragraph under Field of the Invention.)

Claims 6, 7, 8 and 10 claim the method of testing for 25-hydroxyvitamin D binding activity using the components of the kits. The specification teaches the steps required for testing (see pages 6 and 7 beginning at line 16 of page 6) and is summarized at page 12.

GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL:

Rejection under 35 U.S.C. 112, second paragraph.

Do claims 6-8 and 10 fail to identify what is being claimed because they do not identify (1) exactly what is being measured and (2) how it is being measured? Is it necessary, in the claim, to recite how (the method) correlates with salt sensitivity?

Rejection under 35 U.S.C. 103(a) as obvious over DeLucia, et al. (U.S. Patent 4,269,777) and Norman, et al. (U.S. Patent 3,772,150)

Are claims 5, 9 and 11, the kit claims, obvious over DeLucia, et al. ('777) and Norman, et al. ('150)?

ARGUMENTS:

Rejection of claims under 35 U.S.C. 112, second paragraph.

While the amendment presented after final was not entered, said amendment having been amended as suggested by the examiner and so amended merely in an attempt to facilitate prosecution, the claims as now presented are those rejected in the Final Office Action.

The first question is whether the independent claim recites exactly what is being measured. The claim clearly states that what is being measured is the 25 hydroxyvitamin D_3 binding activity in the urine sample, as is clearly stated in the first two lines of claim 6.

The second question under this rejection is whether the claim recites how that which is measured is being measured. It is urged that the art knows how to measure radioactivity as recited in the claims. The steps of preparation of the samples along with the recitation of measurement of radioactivity, a common procedure, would be clearly understood by one of ordinary skill in the art. The claims are written for one

of ordinary skill in the art. Furthermore, the specification clearly teaches how to measure the how the 25 hydroxyvitamin D binding activity is being measured, and the claims are read in light of the description. Hence, it is urged that one of ordinary skill in the art would clearly know what is being measured and how it is being measured.

The third question is whether the claim clearly recites how that which is measured correlates with salt sensitivity. While the claim was amended after final to recite the basis for correlation, it is urged that there is no basis for requiring incorporation of the basic teaching underlying use of the method, namely, the correlation between 25 hydroxyvitamin D binding activity and salt sensitivity, in the claims. No authority for requiring such a recitation in the claim is cited. Hence, it is urged that though the applicant clearly attempted to conform with the examiner's apparent suggestions, applicant believes the claim as presented in the appendix is appropriate and that the basis for performing the measurement need not be recited in the claims.

Claim 10 identifies how the calculations are made and the last phrase identifies exactly what is the purpose of the claimed method, namely, to determine salt sensitivity.

Rejection under 35 U.S.C. 103(a) as obvious over DeLucia, et al. (U.S. Patent 4,269,777) and Norman, et al. (U.S. Patent 3,772,150)

The claim 1 reciting a kit containing radiolabeled 25-hydroxyvitamin D_3, unlabeled 25-hydroxyvitamin D_3 and instructions for measurement of vitamin D binding proteins along with claims 5 and 11 have been rejected over DeLucia, et al. and Norman, et al. The rejection has been traversed by the applicant. DeLucia discloses and claims only methods for making a group of radiolabeled vitamin D compounds and intermediates produced in the methods disclosed therein. There is no teaching therein, nor motivation, to suggest preparation of a kit for any purpose having the components recited in the claims. Though the examiner has urged it would be obvious to make such a kit, it has been impossible to determine where in that reference there would be any motivation or suggestion to make such a product, and the examiner has provided no enlightenment as to where such suggestion or motivation is to be found.

Norman, et al. does not provide any additional motivation or teaching that would, with DeLucia, suggest or motivate one to make the kit of the invention. Norman simply teaches a method of making the metabolites of 25-

hydroxycholecalciferol using mitochondrial preparations. The question is, does the recitation of one prior art ingredient recited in the claim, said ingredient being, in the prior art, in a culture to make metabolites of the ingredient, suggest a kit containing one of the ingredients as a component of a kit? No enlightenment as to this has been provided by the examiner. It is urged by the applicant that the mere recitation of (1) a component of a kit in one prior art reference teaching how to make that component and the recitation of another component (2) recited in the claim in a second prior art reference as a component of a cell culture does not render a kit containing components (1) and (2) obvious for any reason or purpose. Hence, the rejection can not stand.

It is respectfully requested that claims 6, 7, 8 and 10 be deemed to comply with 35 U.S.C. 112, second paragraph as to particularly pointing out and distinctly claiming the subject matter the applicant regards as the invention.

It is also requested that claims 5, 9 and 11 be deemed allowable under 35 U.S.C. 103 as allowable over DeLucia, et al. and Norman, et al. Finally, it is requested that all claims be allowed as amended in the Amendment accompanying this Brief.

Respectfully submitted,

Glenna Hendricks, Reg. 32,535

APPENDIX 1

5. A test kit comprising radiolabeled 25-hydroxyvitamin D_3, unlabeled 25-hydroxyvitamin D_3 and instructions for the measurement of vitamin D binding proteins in urine as a marker for salt sensitivity in individuals.

6. A method of determining specific 25-hydroxyvitamin D binding activity in a urine sample comprising the steps of:

(1) collecting multiple identical samples of urine from an individual;

(2) adding a known amount of radiolabeled 25-hydroxyvitamin D_3 to all samples in step (1);

(3) adding a known amount of excess unlabeled 25-hydroxyvitamin D to half of the samples prepared in step (2) to compete with radiolabeled 25-hydroxyvitamin D_3 for binding proteins in the urine;

(4) incubating all samples prepared in steps (2) and (3) to allow radiolabeled 25-hydroxyvitamin D_3 binding to proteins in the urine;

(5) incubating samples prepared in step (4) with buffered dextran-coated charcoal, then centrifuging to precipitate the unbound radiolabeled 25-hydroxyvitamin D_3;

(6) measuring the average radioactivity in each sample;

(7) subtracting the average radioactivity in the samples containing excess unlabeled 25-hydroxy vitamin D had been added in step (3) with those to which no unlabeled 25-hydroxy vitamin D had been added to determine vitamin D binding proteins in the urine with the amount of binding to samples prepared in step (3) acting as a standard for amount of binding in the samples to which 25-hydroxy vitamin D has not been added.

7. The method of claim 6 wherein the sample tested is human urine.

8. The method of claim 6 wherein high 25-hydroxyvitamin D binding activity in the urine is deemed indicative of salt sensitivity or predisposition to salt-associated hypertension.

9. The kit of claim 5 lacking antibodies to 25 hydroxyvitamin D.

10. A method of calculating specific 25-hydroxyvitamin D binding activity in urine samples of an individual by subtracting binding in samples in the presence of both labeled and excess unlabeled 25-hydroxyvitamin D from binding in samples containing only labeled 25-hydroxyvitamin D_3 but to which no unlabeled 25-hydroxyvitamin D has been added to determine salt sensitivity.

11. The kit of claim 5 containing, additionally, dextran coated charcoal.

Evidence Index:

None

Related Proceedings Index:

None